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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,932	09/26/2003	Matthias Mack	07258-019002 / E2411/US/C	7804

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EXAMINER	
HISSONG, BRUCE D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,932	MACK ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, 25-32, 34-41, and 75-79, drawn to chimeric polypeptides, fusion proteins, nucleic acids encoding said chimeric/fusion proteins, compositions, and kits, classified in class 530, subclass 350, and class 425, subclass 69.1.

II. Claims 42-74, drawn to use of a chimeric/fusion protein to prepare a pharmaceutical composition, and methods of treating a disease with said composition, classified in class 514, subclass 2.

B. The inventions are distinct, each from the other because of the following reasons:

Invention I is related to invention II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the chimeric/fusion proteins of invention I can be used in a materially different process. For example, the chimeric/fusion proteins of group I can be used *in vitro* to isolate and purify their cognate ligands.

C. Additionally, groups I and II are subject to further restriction. It is noted that Group I is drawn to examination of at least one of a number of structurally distinct and non-overlapping chimeric proteins or fusion proteins with binding affinity for distinct ligands. Additionally, Group II is drawn to the use of the chimeric/fusion proteins for the preparation of a composition for

treatment of a number of diseases, and methods of treating a number of diseases. If electing Group I, Applicants are required to further elect:

1. A specific binding affinity for the first polypeptide domain, selected from CCR5, CXCR3, CCR4, CCR6, CCR10, CXCR4, CCR1, CCR2, CCR3, CCR7, CCR8, CCR9, CXCR1, or CX3CR1. Furthermore:

(i) if electing a binding affinity for CCR5, Applicants are required to further elect a chemokine peptide selected from RANTES, MIP-1a, MIP-1b, MCP-2, or MCP-3, or the bispecific antibody defined by SEQ ID NO: 18.

(ii) if electing a binding affinity for CXCR3, Applicants are required to further elect a chemokine peptide selected from IP-10 (CXCL10), MIG (CXCL9), or I-TAC (CXCL11).

2. A second polypeptide domain selected from: a moiety that specifically binds CD3, or binds a toxin selected from *Pseudomonas* PE38 exotoxin, PE40 exotoxin, PE37 exotoxin, or diptheria toxin, or a second moiety that is a toxin selected from *Pseudomonas* PE38 exotoxin, PE40 exotoxin, PE37 exotoxin, or diptheria toxin.

If Group II is elected, Applicants are required to further elect a specific disease or condition selected from latent infection with a primate immunodeficiency virus, inflammatory renal disease, an allergic reaction, inflammatory bowel disease, multiple sclerosis, atopic dermatitis, psoriasis, type I diabetes, transplant rejection, inflammatory joint disease, graft versus host disease, or rheumatoid arthritis.

In order to be fully responsive, applicant is required to further elect a specific binding specificity/moiety for the first and second polypeptide domains if electing Group I, and a specific disease or condition if electing Group II. This is NOT an election of species. The claimed first polypeptide binding affinities and moieties, as well as the second polypeptide domain moieties, are structurally distinct chemical compounds, with different polypeptide sequences, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35

U.S.C. 121. Absent evidence to the contrary, each such polypeptide domain is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. Furthermore, the diseases recited in the claims of Group II represent diseases with different symptoms, pathologies, and underlying causes. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CRF 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct polypeptide domains or diseases represents a serious burden for the office.

D. Applicant is also advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

E. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

F. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

G. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER